UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,146	03/29/2001	Masayuki Machida	10287.39	3956

27683 7590 09/26/2005

HAYNES AND BOONE, LLP
901 MAIN STREET, SUITE 3100
DALLAS, TX 75202

EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/744,146	MACHIDA ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-11 and 35-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-11 and 35-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04/08/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

SDO

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08 April 2005 has been entered.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 8-11 and 35-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. . Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

> To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Vas-Cath, 935 F.3d at 1563; see also Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); In re Gosteli, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

5. For purposes of examination, claims 8-11 and 35-38 have been construed as being drawn to products and not to a method of making same. Further, said claims, in the context of claim 35-38, and claims 8-11 that depend therefrom, have been construed as encompassing any gene, be it complete or partial, from any and all manner of life forms. Said claims have also been construed as encompassing virtually any nucleic acid.

6. Claim 35, while stating that the "target receptor" is a single stranded nucleic acid "second end bonded with [a] carrier particle," has been construed as encompassing nucleic acid that with its bonded either directly or indirectly with said carrier particle. In the case of indirect bondedness, such limitation has been further construed as encompassing both partial and fully double stranded and/or triplex nucleic acid structures. Claims 35 and 8-11 that depend therefrom have also been interpreted as encompassing any and all manner of rRNA, tRNA, and mRNA as well as "single stranded nucleic acid obtained by denaturation of a double stranded nucleic acid or obtained by synthesis." (Claim 35). While the claims have been previously amended so to

remove the limitation that the nucleotide sequence is "predetermined," said claims have been construed as encompassing this very limitation, as well as encompassing nucleic acids for which the nucleotide sequence is unknown.

7. Claims 36 and 37 have been construed as encompassing any double stranded nucleic acid, be it generated by polymerase chain reaction or by some other means. While the claims recite that the nucleic acid is to be the product of a polymerase chain reaction, the claims are drawn to a product and not a process. With the claims fairly encompassing virtually any method of producing nucleic acids, the claims, in turn, have been construed as encompassing any and all possible nucleic acids that can be produced by such methods, regardless of whether the nucleic acid was actually produced by such means, with the caveat that they nucleic acids are bound to the support.

8. The complex of claims 35-37 has also been interpreted as requiring at least two labeling substances bound to different fractions of any number of target receptors and that the labeled complex has a "predetermined molar ration of the types of labeled substances."

9. US Patent 6,465,241 B2 (Haronian et al.), column 14, second full paragraph, teach that the length of axial rise per nucleotide in DNA is 3.3 Angstroms or 3.3×10^{-4} micrometers. In view of this teaching, applicant's single stranded nucleic acid would be 30,303 nucleotides long. Accordingly, applicants nucleic acid of a predetermined base sequence, be it a gene, tRNA, rRNA, mRNA, PCR product, comprising a restriction site at one end, is the product of annealing or of synthesis, would have a length up to 30,303 bases.

10. A review of the disclosure fails to find an adequate written description of any one embodiment where a nucleic acid has a length of 30,303 bases, be said nucleic acid tRNA, mRNA, rRNA, a gene, etc.

11. A review of the disclosure fails to find where any Sequence Listing of any nucleic acid has been provided. Yet, as seen in independent claims 35-37, the claims are drawn to a complex that is required to comprise nucleic acids of a predetermined sequence.

In support of this position, attention is directed to the decision of *Fiers v. Sugano* 25 USPQ2d 1604-5 (CAFC, January 1993) wherein is stated:

> We also reject *Fiers* argument that the existence of a workable method for preparing a DNA establishes conception of that material. Our statement in *Amgen* that conception may occur, *inter alia*, when one is able to define a chemical by its method of preparation requires that the DNA be claimed by its method of preparation. We recognize that, in addition to being claimable by structure or physical properties, a chemical material can be claimed by means of a process. A product-by-process claim normally is an after-the-fact definition, used after one has obtained a material by a particular process. Before reduction to practice, conception only of a process for making a substance, without a conception of a structural or equivalent definition of that substance, can at most constitute conception of the substance claimed as a process. Conception of a substance claimed *per se* without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties. . .
> * * * *
> The difficulty that would arise if we were to hold that a conception occurs when one has only an idea of a compound, defining it by its hoped-for function, is that would-be inventors would file patent applications before they had made their inventions and before they could describe them. That is not consistent with the statute or the policy behind the statute, which is to promote disclosure of inventions.

Attention is also directed to the decision of *University of California v. Eli Lilly and Co.* (CA FC, July 1997) 43 USPQ2d 1398 wherein is stated:

> In claims involving chemical materials, generic formulas usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate written description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian cDNA," without more, is not an adequate written

> description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is See Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what it achieves as a result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.
>
> Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606. (Emphasis added.)

12. The failure of the disclosure to set forth any nucleic acids labeled with different labels in a "predetermined molar ratio," even when the nucleic acids have the same length and differ by but a single nucleotide does not reasonably suggest that applicant had possession of such a complex. Further, the absence of a description of such mandatory components fails to satisfy the written description requirement of 35 USC 112, first paragraph. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

13. For the above reasons, and in the absence of convincing g evidence to the contrary, claims 8-11 and 35-38 are rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement.

Response to argument

14. At page 4 of the response received 11 August 2005, hereinafter the response, applicant's representative asserts:

> [T]he particular nucleic acid sequence of a target receptor of the present invention is of no consequence to the invention. To limit the present invention to any particular nucleic acid would do injustice to what the inventors have invented. The claims specify that the nucleic acid molecules have ends, therefore the claimed nucleic acids are linear, and all nucleic acids are composed of a linear arrangement of known bases. The particular sequence of bases matters not for purposes of the present invention. For purposes of the invention, the nucleic acid simply needs to have an end that can be labeled and/or another end that can be bound to a carrier particle as set forth by the claims.

15. The above argument has been fully considered and has not been found persuasive. Attention is directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

> This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

A critical element of the claimed composition is the "single-stranded nucleic acid target receptors," which are defined in claim 35, for example, as being "a gene, mRNA, tRNA, a single-stranded nucleic acid obtained by denaturation of a double-stranded nucleic acid or obtained by synthesis." It is essential that one be able to readily recognize the members of the genus and thereby determine is a given nucleic acid is thereby encompassed by the claims. It is also essential that the specification "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.*" *Vas-Cath.* As set forth above in *Lilly*: "Thus, as we have previously held, a cDNA is not defined or described by the mere name 'cDNA,' even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA." In the present case, applicant has claimed not only the precursor of cDNA (mRNA), but also claims any gene, tRNA, etc., and hs not provided the first specific description, which is "usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA[, gene, tRNA, single stranded nucleic acid obtained by denaturation of a double stranded nucleic acid or obtained by synthesis.]"

16. While applicant's representative has sought to underpin their argument by reliance upon publications, such showings do not take the place of sworn (declarations/affidavits) evidence and from which assurances that any statements or representations made are correct, as provided by 35 U.S.C. 25 and 18 USC 1001. *Ex parte Gray* 10 USPQ2d 1922 at 1928 (BPAI 1989). Accordingly, applicant's representative's argument is non-persuasive.

17. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 8-11 and 35-38 are rejected under 35 U.S.C. 102(a and e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent 6,124,092 (O'Neil et al.).

22. As noted above, claims 8-11 and 35 have been interpreted as encompassing both direct and indirect bonding of the single stranded nucleic acid to the carrier particle. In the context of indirect bonding, the single stranded nucleic acid could be bound through interaction with a second strand of nucleic acid. Therefore, in opposition to argument raised at pages 11-15 of the response, O'Neil et al., for reasons found below, does anticipate, or at least render obvious the invention of claims 35 and 8-11, which depend therefrom.

23. For purposes of examination, the "single-stranded nuclei acid receptor" has been interpreted as only needing to have a region of single-strandedness, not that the entire length of the receptor is single stranded. Further, the aspect of the target receptor being bound on one end to a carrier particle hs been construed a encompassing direct as well as indirect binding. Similarly, the aspect of the target receptor having a label at the second end has been construed as encompassing both direct and indirect labeling, where indirect labeling encompasses situations where a partially-complementary sequence anneals to the receptor and said complementary sequence has a label at a terminus

24. O'Neil et al., disclose the immobilization of "recovery primers" and "recovery tags" (nucleic acid probes and nucleic acid primers; applicants' "target receptors" and "single-stranded nucleic acids of a predetermined base sequence').

25. O'Neil et al., column 16, provides a listing of various solid supports (applicants' carrier particle) to which one or more nucleic acids are bound.

26. O'Neil, column 11, first full paragraph, teaches that different approaches to using chain terminating nucleotides can be performed, noting specifically that primers can be labeled

differently, or that differently labeled chain terminating nucleotides can be added to a primer extension product.

27. O'Neil et al., column 6, teaches that in one embodiment the nucleic acid can be from 18-36 nucleotides long (primers). O'Neil et al., also discloses performing primer extension reactions, where a fluorescently labeled chain terminator is incorporated into the primer extension product. The aspect of creating a single stranded nucleic acid that is bound to a solid support (carrier) at one end and has a label at the other end (chain terminated sequencing reaction product) is considered to meet the limitation that the immobilized nucleic acids can be of considerably longer length, e.g., tens of thousands of nucleotides long.

28. As seen in columns 5, 6, and 11, the primers, through amplification/synthesis reactions, can have incorporated therein one or more labels. Specifically, there is a "recovery tag," at one end as well as any of a number of detectably-labeled chain terminating nucleotides a the other. The "recovery tag" is used to hybridize to a region of the "target receptor" that has been bound to a support. As presented above, claim 25 has been construed to encompass such an embodiment, an embodiment more clearly articulated in claims 36-38.

29. O'Neil et al., are considered to meet the limitation that the nucleic aids are present in a predetermined molar ratio as they are disclosed as being used in PCR and sequencing assays, which require the usage of known concentrations of reactants. With the receptor and targets of known concentrations, so to then is the label present in known molar concentrations.

30. In the event that O'Neil et al., do not anticipate the claimed invention, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a compound comprising nucleic acids immobilized to a carrier where the nucleic acids are of a

predetermined sequence, are labeled at the end opposite to that bound to the carrier, wherein the label used is present in a predetermined molar ratio as such is disclosed as being useful in conducting hybridization assays, amplification assays, and sequencing assays. While applicant's representative has asserted that the claim 35 now recites the "single-stranded target receptor," that the label is at "the second end", and that claims 36-38 now recite double stranded segments, such limitations, for reasons presented above, have not been found to present convincing evidence of a patentable difference between the claims and the prior art of record. While said representative has provided different motivation, and alternative utility for the claimed product, such does not rise to a patentable distinction. Indeed, a new use for an old product does not make the product patentable. It may, however, be grounds for patenting a new method of using same.

31. For the above reasons, and in the absence of convincing evidence to the contrary, claims 8-11 and 35-38 are rejected under 35 U.S.C. 102(a and e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent 6,124,092 (O'Neil et al.).

Conclusion

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

33. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

34. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
16 September 2005